Remarks

Claims 1-3 are pending. Claims 1 and 3 are cancelled without prejudice to or disclaimer of the underlying subject matter. Claim 2 has been amended and claims 4-7 have been added. Support for the foregoing amendment can be found throughout the specification and claims as originally filed, for example on page 19, lines 1-11. Upon entry of the foregoing amendment, claims 2, and 4-7 will be pending. No new matter enters by way of the foregoing amendment.

I. Restriction

Applicants acknowledge the finality of the restriction requirement but maintain their traversal. To facilitate prosecution, however, Applicants have cancelled the non-elected claims from the application.

Further, Applicants submit that election of a single amino acid sequence is improper and Applicants believe no serious burden would result by the search and examination of at least ten amino acid sequences. The election of a single amino acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 4, October 2005, Section 803.04). The MPEP further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single sequence be selected, no reason has been provided for this deviation from articulated Patent Office policy.

Although Applicants disagree with the election requirement of a single amino sequence, to facilitate prosecution the claims have been amended to reflect the elected SEQ ID NO: 44,293.

II. Priority

The Office asserts that "priority has not been granted to the claimed prior applications, 09/684,016, filed 10/10/2000, and 09/850,147, filed 5/8/2001, for the elected invention because the elected invention was not found to be disclosed in the claimed prior applications." Office Action at page 3. Applicants respectfully disagree with the Office's assertion, and reserve the right to provide evidence that the elected invention is disclosed in the recited applications. In addition, Applicants note that the priority claims has been amended to further include priority as a continuation in part of U.S. Application Serial No. 10/425,115, filed April 28, 2003, which is a continuation-in-part of U.S. Application Serial No. 09/985,678, filed November 5, 2001, which is a continuation of U.S. Application Serial No. 09/304,517, filed May 6, 1999.

III. Specification

The Examiner has requested that trademarks be capitalized and accompanied by the generic terminology. Office Action page 4. Applicants have amended the specification to designate trademarks as such to comply with the Examiner's request.

In addition, the Office alleges that "the title of the invention is not descriptive," and argues that a "new title is required that is clearly indicative of the invention to which the elected claim is directed." Office Action at page 4. Applicants respectfully disagree, however, to facilitate prosecution, Applicants have amended the title to: "RECOMBINANT POLYPEPTIDES ASSOCIATED WITH PLANTS." Accordingly, based on the foregoing, Applicants respectfully request that the Examiner withdraw the objection to Applicants' title.

The Office also asserts that "the creation date (January 20, 2004) listed for both the compact disc containing the sequence listing and that containing Table 1 stated in the specification is not consistent with the date (January 27, 2004) as labeled on the compact discs filed 1/29/04." Applicant's respectfully disagree with the Office's assertion that "it is not clear whether or not the contents of the compact discs filed on 1/29/04 are meant to be incorporated by reference to the specification." However, Applicants note that, to facilitate prosecution, the incorporation by reference of the sequence listing and Table 1 have been amended to refer to the compact discs created on January 27, 2004. As such, Applicants respectfully request withdrawal of the objection to the specification.

IV. Rejection under 35 U.S.C. §101

Claim 2 has been rejected under 35 U.S.C. § 101, allegedly because the "claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility." Office Action at page 5. Applicants respectfully traverse this rejection.

The claimed polypeptide has been disclosed in the specification as having an amino acid sequence encoding a synaptobrevin-like protein. *See, e.g.*, specification at page 10, lines 1-10, Table 1, and the Sequence Listing. The specification provides ample correlation between the claimed amino acid sequence and synaptobrevin-like proteins. Accordingly, the disclosure of the use of the claimed protein as a synaptobrevin-like protein and corresponding uses associated with encoding synaptobrevin-like proteins satisfies the utility requirement of 35 U.S.C. § 101.

The Federal Circuit has recently reiterated that the "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived from the public from an invention with *substantial utility*." *In re Fisher*, 421 F.3d 1365, 1371, 76

U.S.P.Q.2d 1225, 1229 (Fed. Cir. 2005)(citing *Brenner*, 383 U.S. at 534-35)(emphasis in original). The Court noted that since "*Brenner* our predecessor court, the Court of Customs and Patent Appeals, and this court have required a claimed invention to have a specific and substantial utility to satisfy § 101." *Id.* Furthermore, an invention need only provide one identifiable benefit to satisfy 35 U.S.C. § 101. *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983) ("when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown").

Although the Supreme Court has not defined the meaning of the terms "specific" and "substantial", the Federal Circuit has identified a framework for the kind of disclosure an application could contain to establish a specific and substantial utility. *In re Fisher*, 421 F.3d at 1371, 220 U.S.P.Q.2d at page 1230. First, the Court indicated that to provide a substantial utility, the specification should disclose a utility such that "one skilled in the art can use a claimed discovery in a manner which provides some *immediate benefit to the public.*" *Id.* (emphasis original). Second, a specific utility can be disclosed by discussing "a use which is not so vague as to be meaningless," that is that the claimed invention "can be used to provide a well-defined and particular benefit to the public." *Id.*

The specification provides utilities for the claimed polypeptides that are well-defined and provide an immediate benefit to the public. For example, the specification provides that the sequences of the invention can be used for monitoring and modifying synaptobrevin-like protein expression in plants. *See, e.g.*, specification at page 25, line 6 through page 28, line 17 and Table 1. The specification discloses that nucleic acid sequences encoding the synaptobrevin-like protein can be introduced into a plant cell and transcribed using an appropriate promoter with such transcription resulting in the reduction or suppression of the endogenous synaptobrevin-like

protein. *See, e.g.*, specification at page 19, line 12 through page 28, line 17. The modification of the expression can be monitored, for example, using an ELISA assay using specific antibodies to the synaptobrevin-like protein. *See, e.g.* specification at page 25, line 16 through page 26, line 18. Such antibodies can be prepared using the claimed polypeptide sequences. As such, the specification provides specific and substantial utilities for the claimed polypeptide sequence having synaptobrevin-like protein activity.

As the Examiner acknowledges, "it is known that there are different members of the synaptobrevin family." Office Action at page 8. The Examiner appears however to require Applicants to identify the precise properties of the protein, yet provides no support for such an assertion. Use of the polypeptides to encode a synaptobrevin-like protein satisfies the utility requirement.

An examiner must accept a utility by an applicant unless the Office has evidence or sound scientific reasoning to rebut the assertion. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992). "More specifically, when a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted utility, the asserted utility must be accepted by the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such as assertion." Federal Register 66(4):1096, Utility Guidelines (2001). "[A] 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996). Applicants have provided such a reasonable correlation.

The Examiner alleges that "it would have been well known in the art that sequence similarity does not reasonably correlate to similar or identical biological activities. Office Action

at page 7. The Examiner cites Everett *et al.* Nature Genetics 17, 411-422 (1997) and Scott *et al.* Nature Genetics 21, 440-443 (1999) to exemplify that "that assignment of a metabolic gene to a known function based on homology comparisons alone provide improper functional assignment." *Id.* The Examiner does not provide any support for the apparent proposition that a single example of an alleged improper functional assignment based on homology to a known sequence renders all homology-based functional assignments unreasonable.

The claimed polypeptides have been asserted to encode synaptobrevin-like proteins. The specification provides ample correlation between the polypeptide sequence and synaptobrevin-like proteins. The Examiner has provided no support for the assertion that this is not a specific, substantial and credible utility. Accordingly, the assertion of the use of the claimed nucleic acid molecules to encode a synaptobrevin-like protein satisfies the utility requirement of 35 U.S.C. § 101.

The Examiner further has not assessed the credibility of the presently asserted utilities. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re*

Gaubert, 524 F.2d 1222, 1224-25, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personal are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided..."). Here, the Examiner has not even attempted to meet this burden.

Applicants have disclosed a specific, substantial and credible utility for the claimed proteins and fragments thereof. This utility alone is enough to satisfy the requirements of 35 U.S.C. § 101. Because Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case, the rejection under Section 101 is incorrect. Reconsideration and withdrawal of this rejection are respectfully requested.

V. Rejection under 35 U.S.C. § 112, first paragraph, Enablement

Claim 2 stands rejected under 35 U.S.C. § 112, first paragraph as not enabled because the claimed invention allegedly lacks utility. Office Action at page 9. Applicants respectfully traverse this rejection and contend that this rejection has been overcome by the arguments set forth above regarding utility. Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph is improper. Applicants respectfully request reconsideration and withdrawal of this ground of rejection.

VI. Claim Rejections – 35 U.S.C. § 112, 2nd Paragraph, Indefiniteness

Claim 2 stands rejected under 35 U.S.C. § 112, second paragraph as allegedly "being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention." Office Action at page 9.

The Examiner alleges that claim 2 is "not clear whether a recombinant polypeptide molecule or the sequence per se of SEQ ID NO: 44293 (elected) is claimed." *Id.* Applicants

respectfully disagree, however, in order to facilitate prosecution, claim 2 has been amended to recite a recombinant polypeptide comprising an amino acid sequence of SEQ ID NO: 44,293. Accordingly, the indefiniteness rejection is moot and Applicants respectfully request that the Examiner withdraw the indefiniteness rejection.

VII. Claim Rejections – 35 U.S.C. § 102(e)

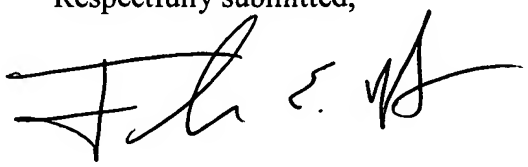
Claim 2 has been rejected under 35 U.S.C. § 102(e) as allegedly "being anticipated by La Rosa et al. (US 20040214272 A1, published application of 10/425,115)." Office Action at page 10. According to the Examiner, "La Rosa et al. disclose a polypeptide with a sequence that is identical to the sequence of SEQ ID NO: 44293 in the instant application." *Id.* Although Applicants disagree with the rejection, to facilitate prosecution, applicants note that the priority of the instant application has been amended to include priority as a continuation in part of U.S. Application Serial No. 10/425,115, filed April 28, 2003, which is a continuation-in-part of U.S. Application Serial No. 09/985,678, filed November 5, 2001, which is a continuation of U.S. Application Serial No. 09/304,517, filed May 6, 1999. As such, U.S. Application Serial No. does not form the proper basis for a 102 rejection.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the claim rejections under 35 U.S.C. § 102(e).

Conclusion

In view of the foregoing remarks, Applicants respectfully submit that the present application is now in condition for allowance, and notice of such is respectfully requested. The Examiner is encouraged to contact the undersigned should any additional information be necessary for allowance.

Respectfully submitted,



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